DOI:
10.12968/ijtr.2018.25.5.215

Document Version
Publisher's PDF, also known as Version of record

Spasticity management with botulinum toxin: A comparison of UK physiotherapy and rehabilitation medicine injectors

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Abstract

Background/Aims: To compare patient outcomes following botulinum toxin (BoNT) injection by either physiotherapy or rehabilitation medicine (medical) professionals over a 3-year period.

Methods: A retrospective, observational cohort study was conducted in a specialised rehabilitation service providing spasticity management including BoNT injection and physical therapy (group therapy, individual therapy, self-exercise, and physical management programmes). Individualised goals were established prior to treatment using goal attainment scaling (GAS) by the multidisciplinary team. The Arm Activity measure (ArmA) was used to evaluate upper limb function and the Modified Ashworth Scale (MAS) used to evaluate spasticity.

Findings: A total of 262 patients were injected. Mean GAS T-score after treatment for the group was 50.2 ± 6.7. GAS T-score for physiotherapy injectors (n=214 (82% of participants)) was 50.2 ± 6.4 and for rehabilitation medicine injectors (n=48 (18%)) 50.3 ± 7.9. No significant differences were identified in terms of goal achievement, upper limb passive function, or spasticity reduction between physiotherapy and rehabilitation medicine injectors. Differences were identified at both baseline (physiotherapist mean 49.7; rehabilitation medicine mean 46.6) and follow-up for active function (physiotherapist mean 49.7; rehabilitation medicine mean 47.8) (ArmA active function subscale; p=0.03). No reportable adverse effects were recorded. No difference in the complexity of injection (e.g. complex clinical presentation, anticoagulation, or technical difficulty) between the injector groups was identified.

Conclusions: Clinical outcomes were comparable between physiotherapy and rehabilitation medicine injectors. No difference in side effect profile or complexity of injection was identified. In this cohort, injection of BoNT by a physiotherapist was as effective in terms of GAS as that undertaken by a rehabilitation medicine physician.

Key words: ■ Botulinum toxin ■ Goal setting ■ Independent prescribing ■ Muscle spasticity ■ Supplementary prescribing

Submitted 23 November 2017; accepted following double blind peer review: 12 March 2018

In the UK, there is a growing policy for non-medical clinicians, such as allied health professionals and nurses, to undertake roles that were previously considered the remit of the medical profession. Examples include prescribing and procedures such as bronchoscopy, gastroscopy, and percutaneous epigastric feeding tube insertion.

Physical management and therapy are key components of spasticity management, and allied health professionals such as physiotherapists and occupational therapists are usually closely involved in the provision of treatment. The UK national guidelines for spasticity management recommend that treatment should be undertaken by an integrated

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'In the UK, as a result of practice development and changes in the scope of practice for some professions, administration of BoNT can be undertaken by any appropriately skilled and trained clinician.'

multidisciplinary team (Royal College of Physicians, 2018). The multidisciplinary model of working has led to different members of the team undertaking a broader range of procedures and the clinical responsibility for their delivery. In other areas of physiotherapy practice, benefit to patient care has been identified by non-medical staff assuming roles that were previously undertaken by medical colleagues (Daker-White et al, 1999).

There is now substantial literature demonstrating that botulinum toxin type A (BoNT) is a safe and effective treatment for spasticity in adults, demonstrating improvement across a wide range of goal areas (Bhakta et al, 2000; Brashear et al, 2004; McCrory et al, 2009; Shaw et al, 2010; Turner-Stokes et al, 2010; Ashford et al, 2015). In the UK, as a result of practice development and changes in the scope of practice for some professions, administration of BoNT can be undertaken by any appropriately skilled and trained clinician. Non-medical clinicians who administer BoNT without prescribing can administer a standard written prescription (Patient Specific Direction), or a Patient Group Direction. Patient Specific Directions are written instructions from an independent prescriber for a medicine to be supplied and administered, to a named patient, by an appropriately qualified health professional. Patient Group Directions are formal documents drawn up by an NHS Trust, providing written instruction for the supply and/or administration of a named medicine, by a named registered health professional, in a defined clinical situation, to a group of patients who may not have been individually identified before presenting for treatment.

Physiotherapists are among the non-medical clinicians who can also now train to prescribe and administer medications. Independent prescribers are specified health professionals (including physiotherapists) defined in law as being able to prescribe medicines independently. To be able to prescribe, the physiotherapist must be listed on the relevant regulatory register and annotated on that register as an independent prescriber, following successful completion of an approved training programme. Supplementary prescribing is also possible for physiotherapists and is a voluntary prescribing partnership between an independent prescriber (usually, though not exclusively, a physician) and the supplementary prescriber, to implement an agreed, patient-specific, clinical management plan (CMP). A CMP can include licensed, 'off-label', and unlicensed medicines. Supplementary prescribers are specified health professionals who have also undertaken the approved training. By implementing these prescribing rights, physiotherapists can prescribe as well as inject BoNT in clinical practice.

Despite these advances in clinical practice and policy, the Summaries of Product Characteristics (SPCs) for the three BoNT products commercially available in the UK (onabotulinumtoxinA, abobotulinumtoxinA, and incobotulinumtoxinA) indicate that administration under the licence is by a physician rather than any qualified clinician, as is currently allowed under UK law. There is a need for manufacturers to update their SPCs to account for developments in practice and prescribing in the UK. It is, however, important to determine whether there is a difference in outcomes and complication rates between medical and non-medical (in the case of this study, physiotherapist) injectors.

This preliminary study aimed to compare patient outcomes following BoNT injection by physiotherapy and rehabilitation medicine practitioners over a follow-up of just over 3 years (December 2011 to January 2015). We hypothesised that, as rehabilitation and injection practice in specialist services should be the same irrespective of who administers the injection, no difference would be seen in outcomes post-intervention between the two injector disciplines.

METHODS

Study design

This was a retrospective, observational cohort study using routinely collected clinical data, conducted in patients who received BoNT (Dysport®; abobotulinumtoxinA) for spasticity management intervention. All participants had a neurological condition with resultant problematic spasticity.

Setting

The study was conducted in a specialised neurological rehabilitation service, providing inpatient, outreach, and outpatient spasticity management for patients with complex needs and, often, more severe spasticity.

Interventions

All participants were undergoing spasticity management, including BoNT injection and physical therapy (group therapy, individual therapy, self-exercise, and/or physical management programmes incorporating input from care and nursing staff). All received BoNT injection and treatment planning with a physiotherapy or rehabilitation medicine injector and the multidisciplinary team.

Medical and physiotherapy injectors had received formal and practice-based training in injection of BoNT and associated procedures (e.g. use of electromyogram for injection). They had also received training in goal-setting (including goal-setting facilitation, negotiation, and application of goal attainment scaling (GAS)) with patients, carers, and the multidisciplinary team, to both clearly identify and then evaluate the aims and outcomes of treatment. Both medical and physiotherapy injectors had over 6 years' experience of injection of BoNT and associated procedures at the start of the study period, as well as advanced knowledge of the wider aspects of spasticity management and rehabilitation. All injectors were independent prescribers as of 2014, when independent prescribing by physiotherapists became possible in the UK. Prior to 2014, administration by a physiotherapist was either by supplementary prescribing or a Patient Group Direction.

Routine data collection was undertaken prospectively as part of an integrated care pathway (ICP) for focal spasticity management in this service. The ICP includes routine recording of the outcome measures used in this study. Injections were performed, as clinically appropriate, under electromyogram guidance and/or electrical stimulation. Comparison of outcomes was undertaken between those patients receiving injections from a physiotherapist and those receiving them from a rehabilitation medicine physician.

Outcome measures

Individualised goals were established prior to treatment, using GAS. In addition, the Arm Activity measure (ArmA) was used to evaluate upper limb function, and the Modified Ashworth Scale (MAS) to evaluate spasticity. A consistent measure of leg function was not routinely applied during the period of this retrospective study (the Leg Activity measure is now routinely used for this purpose). In some individual patients, 10-metre, 6-metre, and 6-minute timed walks were applied, but these data could not be reported for the group as a whole.

The method used for GAS was as described by Turner-Stokes (2009a), based on the original method of Kiresuk and Sherman (1968). In summary, goals are identified to suit the individual and agreed by both the patient (or their carer, if the patient is unable to participate) and the treating team prior to starting treatment. Tightly defined goal definitions are drawn up to be 'SMART' (specific, measurable, achievable, realistic, and timed). Expected (predicted) levels of performance are scored on a 5-point scale ranging from –2 to +2. A score of 0 reflects achievement of the goal as expected, positive scores indicating achievement at higher levels, and negative scores at lower levels than expected. Multiple goals can be combined using a standard formula to derive a T-score reflecting overall achievement of the predicted outcome. If all goals are achieved as predicted, a GAS T-score of 50 will result (scale range 0–100).

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The ArmA is a patient- or carer-rated, 20-item measure of difficulty in passive and active arm function. It comprises a seven-item passive function subscale and a 13-item active function subscale, and uses a Likert scoring system between 0 (no difficulty) and 4 (unable to do task). The passive function subscale scores range from 0 to 28, and the active function subscale scores from 0 to 52. The ArmA has been systematically developed (Ashford and Turner-Stokes, 2013; Ashford et al, 2013a), supporting content validity. It has then been psychometrically tested (Ashford et al, 2013b), providing initial support for construct validity, internal consistency, dimensionality, test–retest reliability, feasibility, and responsiveness. The MAS is a clinical measure of spasticity that is widely used in clinical practice and research (Wade, 1992; Brashear et al, 2002).

Significant complications or side effects, if occurring, were to be reported using the standard clinical adverse event reporting system in the UK.

Analysis

Descriptive analysis of the study participants, including diagnostic category and primary general functional deficits, was completed. Evaluation of overall change in the group was evaluated post-treatment using the Wilcoxon signed-rank test. Comparison of outcomes between medical and physiotherapy injectors was undertaken using the Mann–Whitney U test. The primary outcome measure was GAS, with secondary outcomes of ArmA and MAS.

Goal and muscle classifications were undertaken by two investigators independently and then compared, with agreement on the final categorisation reached. The option for a third reviewer to assess areas of disagreement was available, but not required.

Ethical permission to use clinical data for the purposes of research and evaluation was provided by the NRES Committee—Harrow (ref 04/Q0405/47).

RESULTS

A total of 262 patients received BoNT injections.

Table 1. Diagnosis and impairments of participants (*n*=262) by injector discipline

	Physiotherapy (*n*=214)	Rehabilitation medicine (*n*=48)
Diagnosis		
Acquired brain injury	190 (89%)	43 (90%)
Stroke	74	25
Traumatic	102	16
Other	14	2
Progressive	20 (9%)	5 (10%)
Spinal cord injury	3 (2%)	0
Missing	1 (0%)	0
Global impairment presentation		
Physical	35 (16%)	21 (43%)
Physical/cognitive	20 (9%)	5 (10%)
Physical/communication	34 (16%)	8 (18%)
Physical/cognitive/communication	125 (59%)	14 (29%)
Paresis presentation		
Hemiplegia	98 (46%)	30 (63%)
Monoplegia	4 (2%)	1 (2%)
Paraplegia	9 (4%)	1 (2%)
Tetraplegia	102 (48%)	16 (33%)
Missing	1 (0%)	0

Percentages are per profession (physiotherapy and rehabilitation medicine) and section (diagnosis, global impairment presentation, and paresis presentation)

The mean age of the participants was 53.6 ± 18.6 years, 128 (49%) were male, and 134 (51%) were female. All patients had a neurological condition, with a diagnostic category of either acquired brain injury (*n*=233), progressive condition (*n*=25), spinal cord injury (*n*=3), or missing (*n*=1), and resultant clinical spasticity. Patient demographics are presented in *Table 1*.

No significant side-effects or complications requiring reporting were recorded within the study period. Of the 262 patients receiving BoNT, 214 (82%) received injection by a physiotherapist and 48 (18%) by a rehabilitation medicine physician. The range and frequency of muscles injected by physiotherapy and medical injectors are provided in *Table 2*.

Injection by physiotherapists was undertaken in 28 individual muscles or muscle groups, while injection by rehabilitation medicine physicians was undertaken in 21 muscle groups. A total of 516 muscles in 214 patients (mean 2.4 muscles per patient) were injected by a physiotherapist, while medical physicians injected a total of 141 muscles in 48 patients (mean 2.9 muscles per patient). Despite the difference in the overall number of injections, a similar proportion of muscles were injected per body region (upper limb, lower limb, and head and neck).

Goal and GAS outcome evaluation data were available for 112 patients injected by a physiotherapist and 28 patients injected by a rehabilitation medicine physician. Goal categories were compared between physiotherapy and medical injectors, and are presented in *Table 3*.

Some differences can be seen in the individual goals set and achieved between disciplines. Prevention of deterioration in range of movement was set as a goal in 12% of cases for physiotherapy, and in 44% of cases for rehabilitation medicine. Passive function goals were set in 56% of the physiotherapy group, and in 26% of the rehabilitation medicine group. Active function goals were set in 10% of cases with physiotherapy and 4% with rehabilitation medicine.

The GAS, ArmA, and MAS scales are ordinal in nature; therefore, non-parametric descriptive statistics are presented. However, data were normally distributed; therefore, parametric means are used, as commonly reported with GAS data in other studies. Mean GAS (T-score) for the total group at follow-up was 50.2 ± 6.7. GAS T-score and ArmA and MAS scores at baseline are presented in *Table 4*.

A significant change in GAS T-score was identified between pre- and post-intervention overall. A Wilcoxon signed-rank test showed a significant difference between pre and post-intervention scores (Z= -10.458, *p*=0.005). Median GAS score pre-intervention was 37.6 and post-intervention was 50.0. Mean GAS T-score at follow-up was 50.2 ± 6.4 in the physiotherapist group and 50.3 ± 7.9 in the rehabilitation medicine group.

No significant differences (Mann–Whitney U test) were identified for goal achievement (GAS T-score; p=0.48), upper limb passive function (ArmA passive function subscale; p=0.66), or spasticity reduction (MAS; p=0.29) between physiotherapy and rehabilitation medicine injectors. A difference was identified at both baseline and follow-up for active function (ArmA active function subscale; *p*=0.03). *Table 4* shows the mean baseline scores and *Table 5* shows the mean outcome scores. No significant differences were identified between groups at baseline for any other measures. *Table 5* presents the comparison of physiotherapy and rehabilitation medicine injectors in terms of the outcome measures applied.

No significant difference in the complexity of injection (e.g. complex clinical presentation or technical difficulty) could be identified between the injector groups, based on the database recording form and clinical protocol.

Table 2. Muscles injected by injector discipline (n=262)

Muscle	Physiotherapy (*n*=214)	Rehabilitation medicine (*n*=48)
Upper limb		
Infraspinatus	2 (0.5%)	0
Pectorals (major and minor)	19 (4%)	5 (3%)
Brachialis	47 (9%)	6 (4%)
Brachioradialis	36 (7%)	11 (8%)
Biceps brachii	46 (9%)	12 (9%)
Flexor carpi ulnaris	8 (2%)	4 (3%)
Flexor carpi radialis	4 (1%)	6 (4%)
Flexor digitorum superficialis	69 (13%)	22 (15%)
Flexor digitorum profundus	64 (12%)	11 (8%)
Flexor policis brevis	1 (0.5%)	0
Flexor policis longus	12 (2%)	4 (3%)
Pronator teres	1 (0.5%)	8 (6%)
Lumbricals	0	3 (2%)
Subtotal: upper limb	**309 (60%)**	**92 (65%)**
Lower limb		
Hamstring muscle group (medial and lateral)	68 (14%)	12 (9%)
Adductor magnus and medius	29 (6%)	6 (4%)
Gastrocnemius	22 (4%)	11 (8%)
Soleus	22 (4%)	9 (6%)
Tibialis anterior	10 (2%)	1 (1%)
Tibialis posterior	6 (1%)	3 (2%)
Flexor digitorum longus	7 (1%)	0
Flexor halucis longus	2 (0.5%)	0
Extensor halucis longus	2 (0.5%)	1 (1%)
Quadriceps	5 (1%)	1 (1%)
Subtotal: lower limb	**173 (34 %)**	**44 (31%)**
Head, neck, and trunk		
Trapezius	7 (1%)	0
Sternomastoid	10 (2%)	0
Masseter	8 (2%)	3 (2%)
Latissimus dorsi	6 (1%)	0
Temporalis	0	2 (1%)
Teres minor	1 (0.5%)	0
Scalene	2 (0.5%)	0
Sub-total: Head, neck, and trunk	**34 (6%)**	**5 (4%)**
Total muscles injected	**516**	**141**

Percentages are per profession (physiotherapy and rehabilitation medicine)

DISCUSSION

This study identifies comparable clinical outcomes between physiotherapy and rehabilitation medicine injectors providing spasticity intervention in this specialised rehabilitation service. It is of note that 82% of injections were carried out by a physiotherapist. These findings are important in the context of increasing BoNT administration by physiotherapists and recent developments for independent prescribing in the profession.

Table 3. Proportion of goals set and achieved in the different goal areas by injector discipline

Goal domain	Goal area	Physiotherapy (*n*=112)		Rehabilitation medicine (*n*=28)	
		Number of goals set	Number of goals achieved	Number of goals set	Number of goals achieved
Symptoms and impairment	Pain	35 (17%)	33 (16%)	7 (15%)	5 (12%)
	Involuntary movements	1 (0%)	1 (0%)	1 (2%)	0
	Range of movement (prevention)	25 (12%)	22 (11%)	20 (44%)	16 (35%)
Activities	Passive function	116 (56%)	110 (53%)	12 (26%)	10 (22%)
	Active function	21 (10%)	19 (9%)	2 (4%)	2 (4%)
	Mobility	2 (1%)	2 (1%)	0	0
	Other	9 (4%)	9 (4%)	4 (9%)	4 (9%)
Total*		209 (100%)	196 (94%)	46 (100%)	37 (82%)

**A mean of 1.9 goals per patient for the physiotherapy group and 1.6 goals per patient in the rehabilitation medicine group*

Table 4. Goal attainment scaling, Arm Activity measure and Modified Ashworth Scale scores at baseline by injector discipline

Measure	Physiotherapy (*n*=112)		Rehabilitation medicine (*n*=28)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
GAS (T-score)	36.8 (3.6)	37.6 (0.1)	35.6 (4.5)	37.6 (6.1)
ArmA passive function	14.4 (5.6)	15.0 (9.0)	15.5 (6.6)	15.5 (10.5)
ArmA active function	49.4 (7.6)	52.0 (2.0)	46.6 (12.7)	51.0 (5.5)
MAS	2.9 (0.9)	3.0 (0.0)	2.6 (0.8)	3.0 (1.0)

ArmA: Arm Activity measure; GAS: goal attainment scaling; MAS: Modified Ashworth Scale; IQR: interquartile range; SD: standard deviation

Table 5. Goal attainment scaling, Arm Activity measure and Modified Ashworth Scale scores at 3 years' follow-up by injector discipline

Measure	Physiotherapy (*n*=112)		Rehabilitation medicine (*n*=28)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
GAS (T-score)	50.2 (6.4)	50.0 (0.0)	50.3 (7.9)	50.0 (1.5)
ArmA passive function	10.2 (4.2)	10.0 (6.0)	9.8 (2.9)	9.00 (1.75)
ArmA active function	49.7 (5.8)	52.0 (2.0)	47.8 (4.5)	48.0 (9.75)
MAS	1.2 (0.5)	1.0 (1.0)	1.4 (0.6)	1.0 (1.0)

ArmA: Arm Activity measure; GAS: goal attainment scaling; MAS: Modified Ashworth Scale; SD: standard deviation; IQR: interquartile range

No significant side effects or complications requiring formal reporting were recorded within the study period and, therefore, there was no identifiable difference by injector profession. A difference in the range of muscles injected by physiotherapy and rehabilitation medicine injectors was identified, with injection undertaken by physiotherapists in 28 individual muscles or muscle groups, while injection was undertaken by rehabilitation medicine physicians in 21 muscle groups. No significant difference in the complexity of injection could be identified between the groups. The anticoagulation status of patients was not automatically entered into the database (normally being reported in the patient's clinical notes), and therefore is not reported in the results; however, there was no indication of a difference between professions in the clinical protocol. It is, therefore, likely that the smaller range of muscles injected by a rehabilitation medicine physician is a function of the smaller number of injections undertaken in total by this profession.

In this cohort, injection of BoNT by a physiotherapist was as effective as injection undertaken by a rehabilitation medicine physician. The general rehabilitation and anatomical skills would be expected to be comparable across professions. The specific clinical skills for injection and administration of BoNT, including use of aids to examination such as electromyogram, also seemed comparable based on the clinical outcomes achieved. Physiotherapists should have an advantage in the expertise required for the designing of physical rehabilitation (given core professional expertise) and the management plans required alongside BoNT injection. Conversely, rehabilitation medicine injectors may have advantages in management of patients with complex medication regimens (again, given core professional expertise), which can impact on spasticity management.

Differences were identified between physiotherapy and rehabilitation medicine injectors in the categories of goals set and the rates of achievement in goal areas. However, a slightly greater proportion of injections was carried out for leg spasticity by physiotherapy injectors than rehabilitation medicine injectors, with the converse in the arm, which may account for much of this difference. Some genuine differences may be present, with the physiotherapists setting slightly more functional goals than the rehabilitation medicine physicians, but it is not possible to draw firm conclusions from the current study.

The approach used for spasticity management in these patients was consistent with recommended practice (Royal College of Physicians, 2018). Multidisciplinary goal and treatment planning was undertaken in all cases. Goal-setting using GAS was applied, specifically related to focal spasticity management with BoNT. Patient engagement and satisfaction with goal-setting were not explicitly measured or evaluated in this cohort; however, in common with described practice (Turner-Stokes et al, 2015), patients and carers (where appropriate) were fully engaged in the process and, in particular, directing and evaluating the key aims of treatment. Goal negotiation was nevertheless undertaken to agree goals with the treating team.

'This study, in addition to demonstrating no difference in outcome between injector professions, illustrates the benefits of coordinated interdisciplinary working in spasticity management, encompassing elements of physical management and supplemented by pharmacological interventions, in improving clinical outcomes and achieving patient-centred goals.'

In general, management of focal spasticity with BoNT injection is supported by guideline recommendations (Royal College of Physicians, 2016; 2018), clinical trials (McCrory et al, 2009; Shaw et al, 2010; Turner-Stokes et al, 2010), and cohort study findings (Turner-Stokes, 2009b). In most cases, it is envisaged that it will be necessary to make further recommendations about physical management (or removal of provocative factors for spasticity) prior to pharmacological interventions or in combination with them. This study, in addition to demonstrating no difference in outcome between injector professions, again illustrates the benefits of coordinated interdisciplinary working in spasticity management, encompassing elements of physical management and supplemented by pharmacological interventions, in improving clinical outcomes and achieving patient-centred goals.

Limitations

The current study has some important limitations that need to be addressed in future work. Firstly, the study was conducted in one service offering spasticity management. The service is a specialised, regional service covering a large geographical area with a range of patients and spasticity severity. The service integrates the expertise of specialist allied health professionals and rehabilitation medicine physicians. Many of the patients seen have complex presentations and severe spasticity, which is likely to be reflected in the range of injections applied in this study group and may not translate exactly to other services. Working practices may also differ from other types of service.

Secondly, these data were routinely collected and, therefore, outcome evaluation was conducted with patients and carers by the same clinicians as those providing treatment. This may introduce possible

bias to the outcome evaluation, but this did not differ between physiotherapy and rehabilitation medicine injectors. Also, given the routine nature of data collection, significant goal data were missing; therefore, the strength of this analysis is reduced. Due to the large geographical area covered by this clinical service, patients receiving treatment are often reviewed and followed up by community teams, which has resulted in reduced goal and outcome data. Subsequent to the period covered in this study, further measures have been implemented, such as review by telephone and data collection by local teams, to improve capture of these data.

Thirdly, again due in part to the use of routinely collected data, there is a large disparity in the number of injections carried out per profession. While this is a finding in itself for the service evaluated, it results in limitations with the comparison, for example, in the range of muscles injected, as well as differences in goal classification per category for the professions.

CONCLUSIONS

In this study, comparable clinical outcomes between physiotherapy and rehabilitation medicine practitioners providing BoNT injections as intervention for spasticity have been identified. Some differences were seen in the muscles injected and the categories of goals set, but not in overall outcomes, as measured by the GAS T-score. No difference in side effect profile or the complexity of injections (e.g. complex clinical presentation, anticoagulation, or technical difficulty) was identified. In this cohort, injection of BoNT by a physiotherapist was as effective as that undertaken by a rehabilitation medicine physician in terms of the primary outcome of GAS. **IJTR**

Funding and acknowledgements: Stephen Ashford is funded by the National Institute of Health Research (NIHR), UK, in the form of a Clinical Lectureship award (CAT-CL-03-2012-010). The authors would also like to thank the Dunhill Medical Trust for financial support in the development of this manuscript. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, NIHR CLAHRC NWL, or the Department of Health.

Conflict of interest: none declared.

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